UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

ONLINE PUBLICATION ONLY

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LUCIA BURGOS,

Plaintiff,

-against-

SATIETY, INC.,

Defendant.

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MEMORANDUM AND ORDER

10-CV-2680 (JG)(RLM)

A P P E A R A N C E S:

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JOHN GLEESON, United States District Judge:

Plaintiff Lucia Burgos brings suit against defendant Satiety, Inc. ("Satiety"), alleging violations of the Food, Drug, and Cosmetic Act (the "FDCA"), as well as several state-law parallel claims. Satiety has moved to dismiss the amended complaint. The motion is granted in part and denied in part.

BACKGROUND

In a complaint filed on June 11, 2010, Burgos brought suit against Satiety, alleging that an experimental medical device it had developed for the treatment of obesity had caused Burgos injury in violation of both federal and state law. The device was designed to

allow for stomach stapling without surgery; the stapling mechanism was instead slipped down the patient's throat and esophagus, thereby avoiding the need for an incision. In a memorandum and order dated November 30, 2010, I determined that Burgos's allegations were preempted by the comprehensive federal regulatory scheme administered by the Food and Drug Administration ("FDA") and dismissed the complaint. *Burgos v. Satiety, Inc.*, 2010 WL 4907764, at *3 (E.D.N.Y. Nov. 30, 2010) ("*Burgos I*").[1] However, noting that the federal regulatory scheme "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulation," *id.* (quoting *Riegel v. Medtronic*, 552 U.S. 312, 330 (2008)), I granted Burgos leave to replead her claims as state-law parallel claims. *Id.* at *4.

In an amended complaint filed on December 17, 2010, Burgos sets forth two causes of action: one for negligence and one for negligent manufacture. The new complaint is almost entirely devoid of factual allegations, relying instead upon the facts alleged in the first complaint. Opp. at 2. Satiety has moved to dismiss the amended complaint.[2]

I now grant Satiety's motion in part, and deny it in part. As explained below, the first cause of action remains preempted, and parts of the second do not adequately allege a parallel claim; therefore, Satiety's motion with respect to those sections of the amended complaint is granted. However, Satiety's motion with respect to Burgos's allegations regarding its Investigational Device Exemption ("IDE") and 21 U.S.C. § 351 is denied.

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1 Familiarity with the facts and history of *Burgos I*, as well as with the federal regulatory scheme outlined in that opinion, is assumed here.

2 Although Satiety has moved under Fed. R. Civ. P. 12(b)(6), I construe the motion as having been brought under Rule 12(c) for judgment on the pleadings because Satiety has already answered the amended complaint. *See Dunnigan v. Metro. Life Ins. Co.*, 277 F.3d 223, 227 n.3 (2d Cir. 2002). Also on the procedural front, I note that this is the rare case in which a motion to dismiss (or for judgment on the pleadings) *follows* a successful defense motion for summary judgment. *Burgos I* was a decision on Satiety's motion for summary judgment, but as I explained to counsel in a teleconference on November 10, 2010, that motion would have been more accurately designated as one seeking relief under Rule 12.

DISCUSSION

A. *Motion to Dismiss*

In order to survive a motion for judgment on the pleadings under Fed. R. Civ. P. 12(c), a plaintiff must "state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). In evaluating the plaintiff's claim I construe the complaint liberally, accepting its well-pled factual allegations as true and drawing all reasonable inferences in favor of the non-moving party. *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152 (2d Cir. 2002). Although the complaint must be supported by more than "mere conclusory statements," *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009), it need not provide "detailed factual allegations." *Twombly*, 550 U.S. at 555.[3]

B. *Negligent Manufacture*

In her first cause of action, Burgos alleges that Satiety's TOGA stomach-stapling device failed and perforated her esophagus due to "improper workmanship and error of Satiety at the point of manufacture which took place during the manufacturing process." (Am. Compl. ¶ 22.) She further alleges that the TOGA device had "an impurity, imperfection and/or other product defects . . . [which] was a deviation from Satiety's quality manufacturing standards for the TOGA System," leaving the device in a "defective condition and unreasonably dangerous to plaintiff when it left Satiety's hands." (*Id.* ¶¶ 23-25.) Finally, she alleges that the device "was used in the manner intended." (*Id.* ¶ 27.) Burgos fails to cite any federal statute or regulation to support her claim of negligent manufacture.

This claim again runs afoul of federal preemption doctrine. Because Burgos cites no federal statute or regulation underlying Satiety's alleged negligent manufacture, she does not

3 Although *Iqbal* and *Twombly* dealt with motions brought under Fed. R. Civ. P. 12(b)(6), a motion for judgment on the pleadings under Rule 12(c) is evaluated under the same standard of review as one under Rule 12(b)(6). *Hayden v. Paterson*, 594 F.3d 150, 157 n.4 (2d Cir. 2010).

"allege a state-law cause of action that parallels a violation of the FDCA." *Burgos I* at *3. As was more fully discussed in *Burgos I*, negligent manufacture is one of the many state law tort claims that is preempted by the federal regulatory scheme that governs the testing and approval process for experimental medical devices. *See id.* (claim of negligent manufacture is preempted); *Berish v. Richards Med. Co.*, 928 F. Supp. 185, 192 (N.D.N.Y. 1996) ("A complex structure was set forth to monitor, investigate, record, and, if necessary sanction with withdrawal medical devices granted an IDE. Accordingly, the plaintiff's claim of negligent manufacture is preempted, as it is clear that there was federal law in conflict with state law and Congress had filled the field." (quotation marks omitted)); *Richman v. W.L. Gore & Assocs., Inc.*, 881 F. Supp. 895, 901 (S.D.N.Y. 1995) ("[S]tate law tort claims arising out of defendant's alleged negligent, careless and reckless manufacture, design, construction, labeling, packaging, distribution, and sale of the [device], generally, are preempted."). Count I of the amended complaint is therefore dismissed.[4]

C. *Negligence*

In her second cause of action, Burgos purports to base a negligence claim on conduct that allegedly violated four[5] federal statutes or regulations: 21 U.S.C. § 351 (adulteration of the device) (Am. Compl. ¶ 36); the "terms, conditions, standards and specifications of the [IDE] secured by Satiety from the Food and Drug Administration's [pre-market approval process]" (Am. Compl. ¶ 35); 21 C.F.R. § 812.140 (record-keeping) (Am. Compl. ¶ 37); and 21 C.F.R. § 812.110 (disposal of the device) (Am. Compl. ¶ 38). She alleges that, by violating each

4 Accordingly, I need not determine whether the claim survives scrutiny under *Iqbal* where there are no facts provided to support the allegations that the TOGA device was "manufactured in violation of defendant's quality manufacturing standards for the device," Opp. at 2, nor is there any explanation in either of the complaints or any of the briefing of what those "quality manufacturing standards" might entail.

5 Burgos also cites the FDCA itself, in what appears to be an overview paragraph. (Am. Compl. ¶ 33.) However, if she did intend by her invocation of the FDCA to bring an independent parallel negligence claim under the statute, she includes no specific allegations to support such a claim and therefore it is dismissed.

of these statutes or rules, Satiety breached "a duty of reasonable care" that it owed to her. (Am. Compl. ¶ 31.) She therefore rests her parallel claim of negligence on Satiety's alleged violations of each statute or rule.

1. *The Specific Allegations*

a. *21 C.F.R. § 812 -- The Record-Keeping Requirement*

Burgos cannot state a negligence claim against Satiety arising out of its alleged failure to comply with federal record-keeping requirements. New York law requires a party seeking to allege negligence to establish "(i) a duty owed to the plaintiff by the defendant; (ii) breach of that duty; and (iii) *injury substantially caused by that breach*." *Lombard v. Booz-Allen & Hamilton, Inc.*, 280 F.3d 209, 215 (2d Cir. 2002) (emphasis added). The injury Burgos alleges derives from a flaw in the device itself, and is comprised primarily of "past and future pain and suffering; past and future medical expenses; and lost earnings." (Am. Compl. ¶ 14; *see also id.* ¶ 21 ("As a direct and proximate result of the failure of the Defective Device, plaintiff's esophagus was torn and/or perforated."); ¶ 28 (listing physical and mental injuries).)

Burgos's allegations in the two paragraphs invoking § 812 cannot plausibly support an inference that Satiety's alleged failure to keep adequate records caused the injury she alleges. In paragraph 37 she states merely that "Satiety did not keep adequate records as to the Defective Device, including but not limited to, the disposal of the Defective Device;" and in paragraph 38 she claims that "Satiety did not properly dispose of the Defective Device."[6] Although Satiety's alleged failure to comply with its obligations under § 812 may make a well-

6 Burgos's allegation that Satiety failed to "properly dispose of" the TOGA device used in her procedure is not actionable under 21 C.F.R. § 812.110, which is applicable only to investigators and not sponsors. Satiety, as the manufacturer of the TOGA device (Am. Compl. ¶ 9), is a sponsor and not an investigator. *See* 21 C.F.R. §§ 812.3(i) (defining "investigator"); 812.3(n) (defining "sponsor"). There is no analogous requirement in § 812 that would apply to a sponsor. *See, e.g.*, §§ 812.40, 812.46(b), 812.140(b), 812.150(b).

pleaded claim more difficult to prove, and perhaps even warrant some form of relief at trial,[7] it does not support a negligent manufacture claim. Burgos cannot establish that her injury was "substantially caused" by Satiety's alleged breach of its record-keeping duties.

b. *Claims Based on Satiety's IDE*

Burgos's allegations involving Satiety's IDE, on the other hand, do state a claim under *Iqbal*. As noted in *Burgos I*, IDE devices are subject to "strict requirements regarding design, manufacture, and safety," imposed and monitored by the FDA. *Burgos I*, at *2 (quoting *Elbert v. Howmedica, Inc.*, 841 F. Supp. 327, 330 (D. Haw. 1993)). Specifically, IDE devices must be manufactured in accordance with the "detailed application describing the [device] and the proposed study" that the sponsor originally submitted to the FDA. *Becker v. Optical Radiation Corp.*, 66 F.3d 18, 20 (2d Cir. 1995); *see* 21 C.F.R. § 812.20(b). Any changes in the device's composition or manufacture are subject to strict FDA monitoring, and must be implemented subject to a pre-approved procedure to permit such changes. *See* 21 U.S.C. §§ 360j(g)(2)(C); 360j(g)(6)(A). Changes in manufacturing process must also be reported to the FDA within five days of their implementation. 21 U.S.C. §§ 360j(g)(6)(B)(ii).

In paragraph 35, Burgos alleges that the TOGA device was "manufactured in violation of the terms, conditions, standards and specifications of the [IDE] secured by Satiety." (Am. Compl. ¶ 35.) She does not allege how the TOGA device's manufacture violated the IDE, nor does she specify the terms, conditions, standards, or specifications that she claims were violated. However, at this stage of the proceedings she cannot reasonably be expected to do so, because the information she requires to provide the requisite degree of specificity -- the IDE documentation submitted by Satiety to the FDA -- is confidential and not available to the public.

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7 *See Glover v. Costco Wholesale Corp.*, 153 Fed. App'x 774, 776-77 (2d Cir. 2005) (affirming use of an adverse inference jury instruction where defendant had acted "at least negligently" in failing to maintain a record that it knew or should have known would be relevant to litigation regarding a physical injury).

See 21 C.F.R. § 812.38. If she had the same information that Satiety has, she might well be able to specifically allege ways in which Satiety was negligent in its manufacture of the TOGA device used in her procedure.

In *In re Medtronic*, Judge Melloy of the Eighth Circuit addressed a similar set of circumstances. *In re Medtronic, Inc., Spring Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200 (8th Cir. 2010) (Melloy, J., concurring in part and dissenting in part). He explained that plaintiffs alleging state-law parallel claims based on a violation of a manufacturer's agreement with the FDA often suffer from a unique disadvantage: the agreements (including IDEs) that would provide the necessary factual specificity are confidential, and available only to the defendants and the FDA. Judge Melloy noted the injustice that would arise from a court's decision to "rigidly" adhere to *Twombly*, rather than pragmatically evaluate the complaint in the context of the plaintiff's informational limitations. *Id.* at 1209. Judge Melloy concluded that "a plaintiff's pleading burden should be commensurate with the amount of information available to them." *Id.* at 1212. Other courts have similarly observed that it would be an injustice to penalize a plaintiff for alleging, through no fault of her own, what turned out to be insufficient facts about the manufacturing process of a device that caused injury. *See Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830 (S.D. Ind. 2009); *see also Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010).

Burgos's pleadings are entitled to the liberal reading advocated by Judge Melloy. Although the amended complaint is of necessity somewhat bare-bones, Burgos has diligently alleged as many facts as she can at this point. She alleges that the TOGA device malfunctioned and perforated her esophagus, rather than that human error caused her injury (*see* Am. Compl. ¶¶ 20-22). At oral argument she supported that allegation by reference to the incident report filed

by the TOGA investigation team that performed her procedure. She alleges that the TOGA is an experimental medical device that was required to be manufactured in accordance with its IDE (*see id.* ¶ 35), and she alleges the device did not function as it was intended to function (*see id.* ¶¶ 20-23). She further alleges that the malfunction was "due to improper workmanship and error of Satiety at the point of manufacture . . . ." (*Id.* ¶ 22.)

Accordingly, I conclude that Burgos has stated a claim that Satiety did not manufacture the TOGA device in conformity with the IDE (as it had a duty to do) and is therefore subject to a state-law negligence action. *Twombly* and *Iqbal* do not require that Burgos plead her case with particularity -- all she must do is provide enough facts to support a plausible inference that Satiety has violated the terms of its IDE. *In re Medtronic*, 623 F.3d at 1212 (citing *Hofts*, 597 F. Supp. 2d at 838). This she has done. To require her to do more would be to "turn *Twombly* into an insurmountable hurdle" for a plaintiff whose claims rest on the terms of confidential documents not available in the public sphere. *Id.* Therefore, Burgos is entitled to the limited amount of discovery that would permit her to make a factually-based claim that Satiety's manufacturing process did not comport with its IDE.

Finally, Burgos's entitlement to discovery on her IDE claim extends to the alleged violation of 21 U.S.C. § 351. She alleges that the TOGA device "failed to meet established performance standards," or that the "methods, facilities or controls used for its manufacture and/or installation were not in conformity with federal requirements." (Am. Compl. ¶ 36.) The performance standards and federal requirements referenced in this claim are the ones allegedly contained in Satiety's IDE. *See* Mot. at 13 (noting that 21 U.S.C. § 351(i), which penalizes "failure to comply with requirements under which device was exempted for investigational use," is "the only subsection [of § 351] that could possibly apply to an IDE device"). This allegation

does not seek to impose any obligations on Satiety other than those already imposed by the FDA, but instead seeks damages for Satiety's alleged failure to manufacture the TOGA device in accordance with the FDA's requirements. It therefore states a proper parallel negligence claim.

Burgos's regulatory allegations (Am. Compl. ¶¶ 37-38) are deficient under *Iqbal* and under New York law; however, her statutory allegations (*id.* ¶¶ 35-36) survive. Burgos is entitled to a brief and strictly-cabined period of discovery in order to determine the terms of Satiety's IDE, and to explore whether or not the specific device used in her procedure was manufactured in accordance with the IDE.

CONCLUSION

The defendant's motion is granted in part and denied in part. Judge Mann is respectfully requested to schedule an initial conference to facilitate the limited discovery discussed above.

So ordered.

John Gleeson, U.S.D.J.

Dated: April 5, 2011
Brooklyn, New York